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August 20, 1987

X/14

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RE: Patent Term Extension
Application for
U.S. Patent No. 4,215,215
Issued July 29, 1980

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,215,215, issued July 29, 1980, is eligible for patent term extension under 35 USC 156. The period of extension has been determined to be 2 years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register on February 5, 1987, as follows:

$$\begin{aligned}\text{Period} &= \frac{1}{2} \text{ (Testing Phase)} + \text{Approval Phase} \\ &= \frac{1}{2} (1605) + 651 \\ &= 1454 \text{ days}\end{aligned}$$

Since the regulatory review period began (October 14, 1976) before the patent issued (July 29, 1980), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the determination of the length of the maximum extension. 35 USC 156(c). (From October 14, 1976 to July 29, 1980 is 1384 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period: 2989-1384=1605 days.) No determination of a lack of due diligence was made. 35 USC 156(c)(1). The exception of 35 USC 156(c)(3) does not operate to reduce the maximum period of extension determined above. However, the limitation of 35 USC 156(g)(4)(C) applies in the present situation because Patent No. 4,215,215 was issued (July 29, 1980) before the date of enactment (September 24, 1984) of 35 USC 156; the date of exemption under Section 505(i) of the Federal Food, Drug and Cosmetic Act involving Tegison became effective (October 14, 1976) was before the date of enactment, and the product was not approved for commercial marketing or use (September 30, 1986) before the date of enactment. Since the period of extension calculated under 35 USC 156(c) for Patent No. 4,215,215 and Tegison cannot exceed two (2) years under 35 USC 156(g)(4)(C), the period of extension will be for two (2) years.

A single request for reconsideration of this final determination as to eligibility and the length of extension of the term of U.S. Patent 4,215,215 may be made if filed within one (1) month of the date of this notice. In the absence of such request, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,215,215, a certificate of extension, under seal, for a period of 2 years. The rights derived from the patent during the period during which the patent is extended are defined in 35 USC 156(b).

C.E. Van Horn

Charles E. Van Horn, Director
Patent Examining Group 120

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs
Food & Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Tegison
FDA Docket # 86E-0491